Application No. 10/594,104 Amendment dated May 19, 2009

Reply to Office Action of November 19, 2008

Docket No.: 2004.834US

## Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

## Listing of Claims:

- (Previously Presented) A drug delivery system consisting of one or more compartments and comprising a progestogenic compound dissolved in a thermoplastic polyethylene vinylacetate copolymer whereby,
  - if the delivery system consists of one compartment, the compartment comprises
  - (i) a core of a thermoplastic polyethylene vinylacetate copolymer comprising the progestogenic compound, the progestogenic compound being dissolved in the polyethylene vinylacetate copolymer up to a concentration below the saturation level at 25°C, and an estrogenic compound; and
  - (ii) a skin of a thermoplastic polyethylene vinylacetate copolymer covering the core, the skin being permeable for both compounds;
  - if the delivery system consists of more than one compartment, only one compartment comprises
  - (iii) the progestogenic compound, the progestogenic compound being dissolved in a core of a thermoplastic polyethylene vinylacetate copolymer up to a concentration below the saturation level at 25°C, and an estrogenic compound; and
  - (iv) a skin of a thermoplastic polyethylene vinylacetate copolymer covering the core, the skin being permeable for both compounds.
- (Original) A drug delivery system according to claim 1, wherein the progestogenic compound is a steroidal progestogenic compound and/or the estrogenic compound is a steroidal estrogenic compound.

Application No. 10/594,104 Docket No.: 2004.834US

Amendment dated May 19, 2009

Reply to Office Action of November 19, 2008

(Previously Presented) A drug delivery system according to claim 1, wherein the
polyethylene vinylacetate copolymer of the core is a copolymer containing 30 to 50 wt%
vinylacetate.

- (Previously Presented) A drug delivery system consisting of one or more compartments and comprising a progestogenic compound dissolved in a thermoplastic polyethylene vinylacetate copolymer whereby.
  - if the delivery system consists of one compartment, the compartment comprises
  - (i) a core of a thermoplastic polyethylene vinylacetate copolymer, the copolymer containing 30 to 50 wt% vinylacetate, and the core comprising a progestogenic compound, the progestogenic compound being dissolved in the polyethylene vinylacetate copolymer up to a concentration below the saturation level at 25°C, and an estrogenic compound; and
  - (ii) a skin of a thermoplastic polyethylene vinylacetate copolymer covering the core, the copolymer containing 1 to 15 wt% vinylacetate, the skin being permeable for both compounds, and the skin having a thickness in the range of 10 to 110 μm;
  - if the delivery system consists of more than one compartment, only one compartment comprises
  - (iii) the progestogenic compound, the progestogenic compound being dissolved in a core of a thermoplastic polyethylene vinylacetate copolymer up to a concentration below the saturation level at 25°C, the copolymer containing 30 to 50 wt% vinylacetate, and an estrogenic compound; and
  - (iv) a skin of a thermoplastic polyethylene vinylacetate copolymer covering the core, the copolymer containing 1 to 15 wt% vinylacetate, the skin being permeable for both compounds,
  - and the skin having a thickness in the range of 10 to 110 μm.
- (Previously Presented) A drug delivery system consisting of one or more compartments and comprising a progestogenic compound dissolved in a thermoplastic polyethylene vinylacetate copolymer whereby,

Application No. 10/594,104 Docket No.: 2004.834US

Amendment dated May 19, 2009 Reply to Office Action of November 19, 2008

- if the delivery system consists of one compartment, the compartment comprises

 (i) a core of a thermoplastic polyethylene vinylacetate copolymer, the copolymer containing 30 to 50 wt% vinylacetate, and the core comprising a progestogenic compound,

the progestogenic compound being dissolved in the polyethylene vinylacetate copolymer up to a concentration below the saturation level at 25°C, and an estrogenic compound; and

(ii) a skin of a thermoplastic polyethylene vinylacetate copolymer covering the core, the copolymer containing 14 to 28 wt% vinylacetate, the skin being permeable for both

compounds, and the skin having a thickness of 70 to 250 µm;

- if the delivery system consists of more than one compartment, only one compartment

comprises

(iii) the progestogenic compound, the progestogenic compound being dissolved in a core of a thermoplastic polyethylene vinylacetate copolymer up to a concentration below the

saturation level at 25°C, the copolymer containing 30 to 50 wt% vinylacetate, and an

estrogenic compound; and

(iv) a skin of a thermoplastic polyethylene vinylacetate copolymer covering the core, the copolymer containing 14 to 28 wt% vinylacetate, the skin being permeable for both

compounds, and the skin having a thickness of 70 to 250 µm.

6. (Previously Presented) A drug delivery system according to claim 1, wherein the

progestogenic compound is etonogestrel.

7. (Previously Presented) A drug delivery system according to claim 6 wherein the release on

day 21 of etonogestrel of the drug delivery system is 80  $\mu g$  / day or more.

8. (Previously Presented) A drug delivery system according to claim 1, wherein the estrogenic

compound is ethinyl estradiol.

9. (Previously Presented) A drug delivery system according to claim 1, wherein the system is

ring-shaped.

4

Application No. 10/594,104 Docket No : 2004.834US

Amendment dated May 19, 2009

Reply to Office Action of November 19, 2008

10. (Previously Presented) A drug delivery system according to claim 1, wherein the drug

delivery system consists of one compartment.

11. (Previously Presented) A drug delivery system according to claim 1, wherein the drug

delivery system is a drug delivery system for intravaginal use.

12. (Cancelled)

13. (Previously Presented) A method of manufacturing a drug delivery system according to

claim 9 comprising the steps of:

(i) producing a medicated homogenous polyethylene vinylacetate copolymer core granulate.

comprising a progestogenic and an estrogenic compound:

(ii) co-extruding the core granulate with a polyethylene vinylacetate copolymer skin

granulate, resulting in a copolymer fiber comprising a core covered by a skin; and

(iii) assembling the fibre into a ring.

14. (Original) A method according to claim 13, wherein the core granulate in step (i) is

lubricated with a lubricant.

15. (Previously Presented) A contraceptive kit or kit for hormone-replacement therapy

comprising the drug delivery system according to claim 1.

16. (Previously Presented) A combination preparation to provide contraception whilst

simultaneously to treat a sexually transmitted disease comprising the drug delivery system

according to claim 1.

17-19. (Cancelled)

5

Application No. 10/594,104 Amendment dated May 19, 2009 Reply to Office Action of November 19, 2008

20. (New) A drug delivery system according to claim 1, wherein the drug delivery system is physically stable when stored on or above room temperature.

Docket No.: 2004.834US

- 21. (New) A method of contraception in a female patient, the method comprising:
  - (a) positioning a drug delivery system of claim 1 within the vaginal tract of the patient; and
  - (b) retaining the system within the vaginal tract for at least approximately 21 days.